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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,251	03/04/2002	Kazuya Hosokawa	2462-131US	6081

7590 05/19/2004  
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EXAMINER

MONDESI, ROBERT B

ART UNIT PAPER NUMBER

1653

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/018,251	HOSOKAWA, KAZUYA	
	<b>Examiner</b>	<b>Art Unit</b>	
	Robert B Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☒ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Priority***

The current application filed on February 04, 2002 is a 371 of PCT/JP00/03863 filed on June 14, 2000, which in turn claims priority to foreign application, JP No.11-167453 filed on June 14,1999.

### ***Preliminary Amendment***

The preliminary amendment filed March 14, 2001 has been entered.

### ***Information Disclosure Statement***

The Information Disclosure Sheets (IDS)s filed March 21, 2002, June 20, 2003 and March 08, 2003 have been received and are signed and considered, a copy of the IDS(s) is attached to the following document.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 1-6 and 8** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **Claim 1** cites a substance, which has not been described beyond the fact that it binds itself to a substrate. The applicants have not provided any structural information,

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nor have they provided a sufficient number of examples to meet the written description requirement for the mentioned subject matter- only a few examples of substances that fall within the definition have been provided, i.e, Factor X, IX and VII. **Claims 1-6**, specifically **claims 4-6**, cite modified blood coagulation factors; factor VII, IX and X that have been modified by having one or more amino acids deleted, substituted or added in particular with regards to a serine residue. Griffin et al. in the specification of their US Patent, specifically in the segment titled detailed description of the invention, provide a variety of altered blood coagulation factors capable of binding and inhibiting the original unaltered coagulation factor . However the applicant fails to provide, in the specification of the present application, a written description of such modified blood coagulation factors, indicating that the inventor did not possess the invention at the time of filing of the present application.

**Claim 7** is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In **claim 7** the applicant cites a method of modifying a blood coagulation factor using a synthetic inhibitor such as PMSF and an alkali treatment at a pH in the range of 11.0-13.5. However in the examples 1-3 presented in the specification on pages 21-24, PMSF is used in the method of invention at pH in the range of 7-8. Griffin et al. in the specification of their US Patent, specifically in the section

titled Inhibition of APC by synthetic Peptides Derived from PC (column 41-58) provide a written description of all the steps of the method of their invention. However the applicant fails to provide, in the specification of the present application, a written description of all the method steps of the claimed invention, indicating that the inventor did not possess the invention at the time of filing of the present application.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-3 and 6** are rejected under 35 U.S.C. 102(b) as being anticipated by Berkner et al WO 02/15686 (cited in the IDS filed March 21, 2002). Berkner et al. disclose a blood coagulation factor VII that has been formed by anhydridizing the active serine residue site (Examples 1-3, pages 18-26) (**Present claims 1-3 and 6**). Thus Berkner et al. teach all the elements of **claims 1-3 and 6** and these claims are anticipated under 35 USC 102(b).

**Claims 1-5 and 8** are rejected under 35 U.S.C. 102(b) as being anticipated by Griffin et al. United Patent 5,679,639. Griffin et al. disclose activated blood coagulation factors IX and X that have modified serine residues in order to inhibit the activity of the corresponding non-modified factors IX and X (column 9, lines 14-20 and 58-64; column 13, line 38, lines 39-44) (**Present**

**claims 1-5).** Griffin et al. also disclosed that the polypeptide of their invention can be coupled with a carrier (column 14, lines 12-59) (**Present claim 8**). Thus Griffin et al. teach all the elements of **claims 1-5 and 8** and these claims are anticipated under 35 USC 102(b).

**Claim 7** is rejected under 35 U.S.C. 102(b) as being anticipated by Skogen et al. Skogen et al. teach a method of modifying anticoagulant blood factor Xa comprising using the synthetic inhibitor PMSF (Page 2307, lines 3-10). Thus Skogen et al. teach all the elements of **claim 7** and this claim is anticipated under 35 USC 102(b).

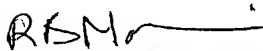
### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Robert B Mondesi  
Patent Examiner  
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5-12-04



**ROBERT A. WAX  
PRIMARY EXAMINER**